

Case Western Reserve University (CWRU)

Guidelines for Determining Whether a Proposed Activity Meets the Definition of Human Subject Research

The current federal regulations governing human subject research were initially designed in response to concerns about protecting individuals who might unwittingly subject themselves to harmful scientific and medical experiments. However, in reality these regulations apply to all activities that meet the definition of **human subject research**. In addition, CWRU, like most research universities, applies the federal regulations to human subject research, **regardless of the source of funding**. Therefore, it is important for faculty and staff to determine, **prior to initiating such activities**, whether these activities can be defined as human subject research and hence subject to certain university policies and federal regulations.

In practice, for certain non-medical activities in particular, it may be difficult to determine whether the proposed activity meets the definition of human subject research. There are clearly situations where the decision to define an activity as “human subject research” is not “black and white”, but based on reasoned judgment. It is to this end that the following guidelines were developed.

To determine whether your proposed activity meets the federal definition of human subject research (and therefore **may** need to be reviewed by the CWRU IRB or an IRB at one of CWRU’s affiliated hospitals), please answer the following questions. Please note that for an activity to be considered human subject research (and hence requiring at least a review by the respective IRB office, if not by the full IRB, before starting the activity) questions 1 and 2 below must **both** be answered “yes” and either question 3 or question 4 must be answered “yes”.

1. Is the proposed activity a systematic investigation?

A systematic investigation is one that involves a predetermined method for studying a specific topic, answering a specific question(s), testing a specific hypothesis(es), or developing theory.

Examples of systematic investigations include, but are not limited to, observational studies, interview (including those that are open-ended) or survey studies, group comparison studies, test development, program evaluation, interventional research.

Examples of activities that would **not** normally be considered systematic investigations include, but are not limited to, training activities (e.g., human subjects being trained to perform a certain technique or therapy such as art therapy, psychoanalysis, oral history techniques), classroom exercises involving human subjects or human subject data where the objective of the activity is to teach proficiency in performing certain tasks or using specific tools or methods.

2. Will the proposed activity develop or contribute to generalizable knowledge?

To develop or contribute to generalizable knowledge requires that the results (or conclusions) of the activity are intended to be extended beyond a single individual or an internal program.

Examples of activities that are typically not generalizable include biographies and service or course evaluations, unless they can be generalized to other individuals, services, courses or concepts **and there is an intention to do so**. In addition, classroom exercises solely to fulfill course requirements or to train students in the use of particular methods or devices would also not typically be considered generalizable.

Activities involving human subjects or human subjects data where there is an intention to publish the results in a peer-reviewed journal or to present at a regional or national meeting are generally assumed to be generalizable. In addition, theses or dissertation projects conducted to meet the requirements of a graduate degree are usually considered generalizable.

3. Will the proposed activity involve collecting data through an interaction or intervention with a living individual?

Examples of such interactions or interventions include interviews, questionnaires, surveys, observations, manipulation of subject behavior or environment, physical measurements, specimen collection (e.g., blood, tissue), administration of experimental drugs or devices. Please note that the activity must involve a **living individual**.

4. Will the proposed activity involve collecting private identifiable information about a living individual?

Private identifiable information includes **individually identifiable** information from a **living individual**:

- a) about behavior when the individual can reasonably expect that no observation or recording is taking place;
- b) or information that has been provided for specific purposes that the individual can reasonably expect will not be made public (e.g., medical record, employee or student records)

Examples of individual identifiers include the subject's name, address, phone number, social security number, medical record number, student or employee identification number, or, in some cases, the combination of data such that they can identify a single individual through deductive reasoning. For example, data about employer, job title, age and gender may not individually identify a subject, but, when combined, could in certain cases identify a specific individual.

If the information can not be linked to a living individual, or is considered public or is given with the expectation that it will be made public and that it will be linked to the individual (e.g., biography, news story), then it would not be considered private identifiable information.

Use of these guidelines:

As stated previously, there may be a fair amount of ambiguity in certain situations as to whether the activity meets the definition of human subject research. In addition, although the activity may meet the definition of human subject research, it may be exempt from IRB review. The Office of Research Compliance or the relevant IRB office is available for consultation in applying these guidelines to a specific activity and for determining whether a human subject research activity is exempt from IRB review. Please contact Christian LaMantia (216-368-4513) or the relevant IRB office for assistance.

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Application of the Decision Aide for Human Subject Research to Selected Activities

1. Biography of Winston Churchill

This activity is not human subject research, since the individual is no longer alive. [It may also not meet the definition of human subject research since the results of the activity are not intended to be generalizable beyond Winston Churchill].

2. Biography of Bill Clinton

This activity is not human subject research, since the results of the activity are not intended to be generalizable beyond Bill Clinton.

3. Study of the impact of the Great Depression on the lives of African Americans by interviewing a sample of African Americans in Cuyahoga County using an open-ended interview methodology

This is human subject research, since it is a systematic investigation that intends to produce generalizable results and identifiable data will be collected from living individuals.

4. Study of the population trends and the economic viability of major American cities using 1990 and 2000 census data without any unique subject identifiers.

This is not human subject research since no individually identifiable information is being used.

5. The development of a training videotape showing how to conduct a structured interview to assess mood disorders

This is not human subject research, since it is not a systematic investigation.

6. Study of the media preferences and communication styles of normal adults using a mailed questionnaire

This is human subject research since it is a systematic investigation to yield generalizable knowledge by interacting with living individuals

7. Study of communication styles of politicians by analyzing content and delivery of videotaped public speeches of regional and national politicians.

This is not human subject research, since it does not use private identifiable information. The data is derived from public speeches.

8. A study to evaluate the effectiveness of the delivery of social services to home-bound senior citizens by analyzing data collected by the Ohio Department of Health and Human Services and conducting telephone interviews with a sample of senior citizens.

This is human subject research since it is a systematic investigation that is generalizable and interactions with living individuals are planned. In addition, the ODHHS data may also contain subject identifiers.

9. A study of the lives of early Amish settlers in Pennsylvania and Ohio by analyzing diaries, letters, and other written communications.

This is not human subject research since it does not involve living individuals.

10. A study of consumer behaviors while shopping on-line for fashion apparel, and a comparison of satisfaction with the consumption experience of apparel between products purchased on-line and at retail stores.

This is human subject research since it is a systematic investigation that is intended to yield generalizable knowledge and it involves collecting data through interactions with living individuals.

11. A study of whether a particular protein is a biological risk factor for breast cancer by examining tissue discarded from breast biopsies where the identify of the person from whom the biopsy is taken is unknown. However, whether the individual did or did not have breast cancer is known.

This is human subject research since it is a systematic investigation that is intended to yield generalizable knowledge and it involves collecting data through an interaction with a living individual.